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COLEMAN SUDOL SAPONE
714 COLORADO AVENUE
BRIDGEPORT, CT 06605

EXAMINER	
LAM, ANN Y	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LARRY A. SKLAR, TIONE BURANDA
BRUCE S. EDWARDS, CARLOS M. GALLEGOS, W. COYT JACKSON,
FREDERICK W. KUCKUCK, GABRIEL P. LOPEZ,
and ANDREA A. MAMMOLI

Appeal 2007-4355
Application 10/021,243
Technology Center 1600

Decided: January 03, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a microfluidic mixing apparatus, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

DISCUSSION

1. CLAIMS

Claims 1-50 are pending and on appeal. The claims subject to each rejection have not been argued separately and therefore stand or fall

together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, which reads as follows:

1. A microfluidic mixing apparatus comprising:

first driving means for driving a plurality of reagent samples from a plurality of respective source wells into a first fluid flow stream;

second driving means for introducing a separation gas between each of said plurality of reagent samples in said first fluid flow stream to produce a gas-separated first fluid flow stream;

means for driving a second fluid flow stream comprising a plurality of particles;

a junction device downstream of said first driving means and said second driving means, said junction device comprising:

a first inlet port for receiving said gas-separated first fluid flow stream;

a second inlet port for receiving said second fluid flow stream;

a first reaction zone for forcing an initial mixing between said gas-separated first fluid flow stream and said second fluid flow stream to thereby form a reaction product stream; and

an outlet port for allowing said reaction product stream to exit said junction device;

a second reaction zone downstream of said junction device where said plurality of reagent samples and said plurality of particles further mix and form a plurality of reaction products, said second reaction zone communicating with said outlet port; and

means operatively connected to said outlet port and said second reaction zone for selectively analyzing said reaction product stream for said reaction products.

Claim 1 is directed to a "microfluidic mixing apparatus." The Specification defines "microfluidic" to mean "the process where contents of two samples are mixed in a mixer. The bubbles separate discrete sample units. The pulsatile action in the fluid forces the discrete samples to mix with the continuously supplied material." (Spec. 7: 19-22.)

The apparatus of claim 1 comprises two driving means for driving a gas-separated fluid flow stream made up of reagent samples (driven by the first driving means) separated by pockets of separation gas (driven by the second driving means). The apparatus also comprises a "means for driving a second fluid flow stream comprising a plurality of particles." "The term 'particles' refers to any particles such as beads or cells that may be detected using a flow cytometry apparatus" (Spec. 8: 28-29).

The two fluid flow streams meet in a "junction device" that comprises inlet ports for each of the fluid flow streams, a "first reaction zone for forcing an initial mixing between" the two streams, and an outlet port. The junction device can be, for example, a T or Y junction (Spec. 13: 10-13).

The apparatus of claim 1 also comprises a "second reaction zone" in communication with the outlet port, where the contents of the two streams further mix, and a means for analyzing the mixed products.

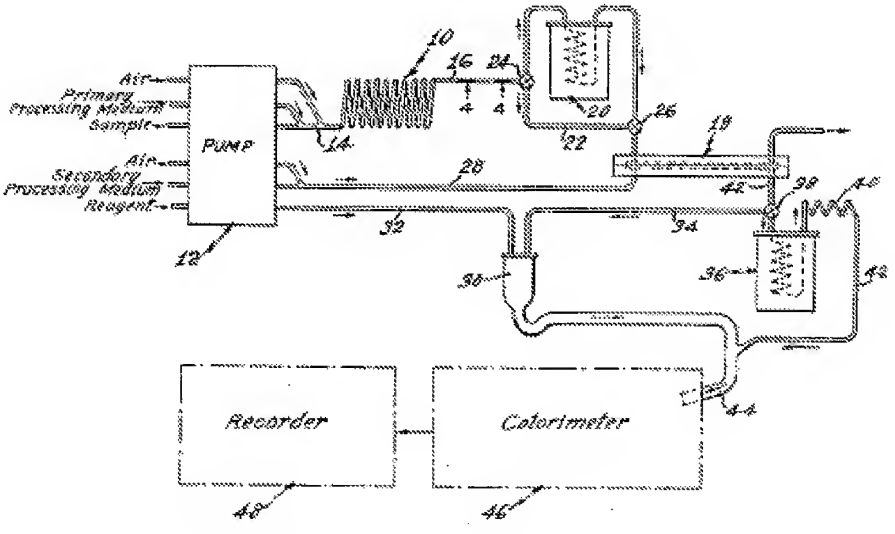
2. OBVIOUSNESS I

Claims 1, 16-39, 42-44, 46, 47, 49, and 50 stand rejected under 35 U.S.C. § 103 as obvious in view of Ferrari[1] and Kercso.[2] (Answer 3, 9.) The Examiner cites Ferrari as "disclos[ing] the invention substantially as claimed" (Answer 3) but interprets the "microfluidic" language in the

[1] Ferrari, US 2,933,293, Apr. 19, 1960.
[2] Kercso et al., US 6,132,685, Oct. 17, 2000.

preamble of claim 1 to mean that the claimed apparatus is "a small device" (*id.* at 5). The Examiner cites Kercso as "teach[ing] a diagnostic device for analyzing samples that is a microfluidic device" (*id.*) and concludes that it would have been obvious "to form the Ferrari device in the microscale as taught by Kercso" to allow "testing a large number of sample compounds with a compact sample handling arrangement" (*id.* at 6).

We agree with the Examiner that the cited references support a prima facie case of obviousness. Ferrari's Figure 1 is reproduced below:



Ferrari states that the figure shows a "body fluid analyzer apparatus" that includes mixing device 10 (Ferrari, col. 1, l. 22 and col. 2, l. 2). The apparatus is disclosed to function as follows: blood samples are combined with a primary processing medium and separated by pockets of air by pump 12 (*id.* at col. 2, ll. 7-12); the blood and primary processing medium are mixed in each sample during its passage through mixing apparatus 10 (*id.* at col. 2, ll. 48-66); and the samples then pass through valves 24 and 26 to reach dialyzer 18 (*id.* at col. 2, ll. 19-24).

Meanwhile, in a second line (28), pump 12 dispenses aliquots of a secondary processing medium separated by pockets of air (*id.* at col. 2, ll. 25-28). The blood samples (mixed with primary processing medium) meet aliquots of secondary processing medium in the dialyzer, where they are separated by the dialysis membrane, "resulting in the separation from the body fluid of the crystaloid constituents thereof, the protein or other non-crystaloid constituents being exhausted" from the dialyzer (*id.* at col. 1, ll. 28-35). Ferrari refers to Skeggs[3] for a fuller description of the apparatus itself (Ferrari, col. 1, ll. 21-25). Skeggs states that "crystaloid constituents" of blood include glucose (Skeggs, col. 3, ll. 35-39).

Thus, in Ferrari's apparatus, each aliquot of secondary processing medium picks up glucose (among other things) from a blood sample in the dialyzer 18. The glucose-containing aliquots of secondary processing medium then pass through valve 38 and along tube 34 to the color development chamber 30 (Ferrari, col. 2, ll. 32-35). Simultaneously, a color development reagent is pumped via line 32 to color development chamber 30 (*id.* at col. 2, ll. 29-31), where it mixes with the aliquots of glucose-containing secondary processing medium, and the aliquot/reagent mixtures then travel through tube 44 to colorimeter 46 (*id.* at col. 2, ll. 44-46).

We agree with the Examiner that Ferrari's apparatus comprises all of the structural elements of claim 1. Ferrari's pump 12 meets the "first driving means," "second driving means," and "means for driving a second fluid flow stream" limitations of claim 1 because it drives "reagent samples" (blood samples or aliquots of secondary processing medium) separated by pockets

[3] Skeggs, US 2,797,149, June 25, 1957.

of air, and also drives a second fluid flow stream (reagent), as required by claim 1.

Ferrari's apparatus also meets the "junction device" limitations recited in claim 1. It comprises a first inlet port (the port at which line 34 meets mixing chamber 30), a second inlet port (the port at which line 32 meets mixing chamber 30), a reaction zone (mixing chamber 30 itself), and an outlet port (at the bottom of mixing chamber 30 that meets the line leading to supply tube 44).

Finally, Ferrari's apparatus comprises a "second reaction zone" (supply tube 44) and a "means . . . for selectively analyzing" the reaction product stream (colorimeter 46).

The Examiner relies on Kercso as evidence that a person of ordinary skill in the art would have considered it obvious to scale down Ferrari's apparatus to a small size (Answer 6). Appellants do not dispute the Examiner's reasoning on this point.

Appellants argue, however, that Ferrari's color development chamber does not meet the limitations of claim 1 because, while the chamber has two inlet ports, "neither of those ports receives a gas-separated sample stream. The samples do not pass through the dialyzer and accordingly cannot arrive at the color development chamber" (Appeal Br. 8). See also the Reply Brief, pages 1-2:

> [T]he gas-separated aliquots of liquid fed to the right inlet port of element 30 in the Ferrari device are not samples from respective source wells, as set forth in appellants' claim 1. Rather, the gas-separated samples (S1, S2, S3) in the device of Ferrari that correspond to appellants' gas-separated samples are separated or isolated by the dialyzer from the flow stream

> entering the right inlet port of element 30. The device of Ferrari does not have a flow structure that permits feeding of the samples (S1, S2, S3) to the element 30.
>
> . . . The word "mixing" means that the entire samples in the first fluid flow stream (S1, S2, S3 in Ferrari) are completely combined with respective portions of the second fluid flow stream.

We do not agree with Appellants' interpretation of the claim language. Claim 1 recites a "junction device . . . comprising: a first inlet port for receiving said gas-separated first fluid flow stream." The first fluid flow stream is made up of "a plurality of reagent samples" separated by gas.

Thus, claim 1 does not require that the first fluid flow stream comprise "blood samples" or "body fluid samples," but "reagent samples." The Specification states that "the term 'reagent sample' refers to a fluid solution or suspension containing solids, such as beads to which a reagent has been bound, to be mixed with 'particles' using a method and/or apparatus of the present invention" (Spec. 9: 22-25).

Ferrari's apparatus is "utilized for analyzing body fluids with respect to critical constituents thereof" (Ferrari, col. 1, ll. 18-19), such as glucose or urea (*see* Skeggs, col. 1, ll. 63-66). These "crystaloid constituents" are contained in the blood samples that are pumped via tube 14 but cross the membrane of the dialyzer 18 and are transferred to aliquots of secondary processing medium pumped via tube 28. The aliquots of secondary processing medium that have absorbed crystaloid constituents from individual blood samples reasonably appear to be "fluid solution[s] . . . to be mixed" in the mixing chamber 30 of Ferrari's apparatus.

"During examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000). Under the broadest reasonable interpretation of claim 1, and consistent with the definitions in the instant Specification, "reagent samples" include the aliquots of modified secondary processing medium that are mixed with reagent in Ferrari's mixing chamber 30.

We agree with the Examiner that the apparatus disclosed by Ferrari includes all the structural elements recited in claim 1, arranged as recited in the claim. We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103 based on Ferrari and Kercso. Claims 16-39, 42-44, 46, 47, 49, and 50 fall with claim 1.

3. OBVIOUSNESS II

Claims 2-15, 40, 41, 45, and 48 also stand rejected under 35 U.S.C. § 103, as follows:

- Claims 2 and 3 as obvious in view of Ferrari, Kercso, Holzapfel[4] and Choperena;[5]
- Claims 2 and 4-15 as obvious in view of Ferrari, Kercso, and Saros;[6]
- Claims 40 and 41 as obvious in view of Ferrari, Kercso, and Manns;[7]
- Claim 45 as obvious in view of Ferrari, Kercso, and Yon-Hin;[8] and

[4] Holzapfel et al., US 5,958,148, Sept. 28, 1999.
[5] Choperena et al., US 5,846,491, Dec. 8, 1998.
[6] Saros et al., US 4,853,336, Aug. 1, 1989.
[7] Manns, US 5,679,310, Oct. 21, 1997.
[8] Yon-Hin et al., US 6,440,645 B1, Aug. 27, 2002.

- Claim 48 as obvious in view of Ferrari, Kercso, and Knapp.[9]

With respect to these rejections, we agree with the Examiner's reasoning and his conclusion that the dependent claims would have been obvious in view of Ferrari and Kercso, combined with the other cited references.

Appellants rely on their arguments with respect to claim 1 to support the patentability of the dependent claims. For the reasons discussed above, we are not persuaded by these arguments. We therefore affirm the rejections of claims 2-15, 40, 41, 45, and 48 under 35 U.S.C. § 103.

[9] Knapp et al., US 6,235,471 B1, May 22, 2001.

SUMMARY

We affirm all of the rejections on appeal.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

dm

Coleman Sudol Sapone
714 Colorado Avenue
Bridgeport, CT 06605